



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

07/21/2015

**MEMORANDUM**

**SUBJECT:** J15-0031 MCAN Human Health Effects Review

**FROM:** Ronald E. Ward Ph.D., Microbiologist/Immunologist  
RAD/AB5 (7403)

**TO:** Gwendolyn McClung Ph.D., Technical Integrator  
RAD/AB3 (7403M)

[REDACTED]

**Conclusion:** The concern for potential human health effects caused by the MCAN microorganism, a strain of *Saccharomyces cerevisiae* [REDACTED], used to make fuel ethanol, is low.

**Title:** MCAN TS0VSMC9—Contained Use of a Genetically Modified *Saccharomyces cerevisiae* Strain for Use in Production of Ethanol

**Submitter:** Danisco US Inc. Rochester NY

**Basis for Conclusion:**

The recipient strain for the MCAN submission is *Saccharomyces cerevisiae* (1). Based on a risk assessment performed by the USEPA, this recipient microorganism has an extensive history of safe use. *Saccharomyces cerevisiae* is non-pathogenic and non-toxic.

The introduced genetic material also does not present health-related concerns. [REDACTED]

[REDACTED]. The new strain, [REDACTED], will be used primarily in the manufacture of fuel ethanol. Because the company uses personal protective equipment (lab coats, safety glasses, latex or nitrile gloves, uniforms, and respirators) during manufacturer, there is low concern for exposure and allergy due to the submission microorganism.

No antibiotic resistance markers remain in the final organism (2). Therefore, there is low concern for antibiotic resistance genes spreading in the environment.

**References**

1. Segal M. Identification Report J-15-0031
2. Segal M. Genetic Construction Report J15-0031